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09/871,607	05/31/2001	Timur Yarovinsky	UIA-031.01	1145

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EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/871,607

Applicant(s)

YAROVINSKY, TIMUR

Examiner

Carla Myers

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the amendment filed April 14, 2003. Claims 3 and 11-20 have been cancelled. Claims 1, 2, 4-10, 21 and 22 are pending. Applicants arguments and amendments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

Claim Objections

2. The specification is objected to because the assigned SEQ ID NOs have not been used to identify each sequence listed, as required under 37 CFR §1.821(d). See for example, page 13 of the specification and the description of the figure 1, which contains nucleic acid sequences.

In the response of April 14, 2003, Applicants did not specifically address this objection. Accordingly, the objection is maintained for the reasons stated above.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Cheng (reference "C1"). This rejection now applies to newly added claim 21.

Cheng (page 11591) teaches a labeled nucleic acid consisting of:

5-'CGTGTGCG**CCCTT**ATTCCC-3'. This nucleic acid comprises a topoisomerase I cleavage motif (i.e., CCCTT) which is not more than 10 bases from the 3' end of the nucleic acid. Additionally, the sequences 5' of the CCCTT meets the limitations of the claim in that the these sequences constitute a polypeptide tag encoding sequence, a terminator sequence, a fusible protein encoding sequence, and a sequence that is within some intron sequence.

RESPONSE TO ARGUMENTS:

In the response of April 14, 2003, Applicants state that the rejection has been obviated by the amendments to the claims. However, the nucleic acid of Cheng anticipates the claimed nucleic acid. As discussed in the above rejection, Cheng teaches a nucleic acid containing a CCCTT sequence within 10 nucleotides of the 3' terminus of the nucleic acid. The sequence 'CGTGTGCG' is considered to comprise a sequence that is within one of the multitude of introns which exist and also comprises a sequence which may be used as a polypeptide tag encoding sequence, a terminator sequence, or a fusible protein encoding sequence.

5. Claims 4-10 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hudson (GenBank Accession No. G06435). This rejection now applies to newly added claim 22.

Hudson teaches a nucleic acid which comprises each of the nucleotide sequences required by claims 4-10. In particular, the nucleic acid of Hudson comprises:

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a) a topoisomerase I cleavage site having a 5' end consisting of TCCT and a 3' end consisting of "T", a palindrome of 2 nucleotides, GC, 3' to the 3' terminus of the topoisomerase I cleavage site, and an "A" nucleotide complementary to the 3' nucleotide of the topoisomerase I cleavage site (see nucleotides 229-237); b) a GATC Sau3A I restriction endonuclease site (see nucleotides 117-120); c) an AGCT sequence that is complementary to a 5' overhang sequence of a Sal I cleavage site (see nucleotides 23-26); d) an AGGA sequence complementary to the 5' end of the topoisomerase I cleavage site (see nucleotides 29-32 and 187-190); and e) a sequence 5' of the topoisomerase I cleavage site which contains nucleotides which have the ability to function as a mutational sequence, a polypeptide tag encoding sequence, a nucleic acid tag sequence, a terminator sequence, a fusible protein encoding sequence, and a sequence that is within some intron sequence. With respect to newly added claim 22, the nucleic acid of Hudson further includes a CCCT topoisomerase cleavage sequence and a T 3' to this cleavage sequence (see nucleotides 249-253).

RESPONSE TO ARGUMENTS:

In the response of April 14, 2003, Applicants state that the rejection has been obviated by the amendments to the claims. In particular, Applicants state that the rejection has been overcome by the amendment to the claims to recite that the topoisomerase cleavage site is within 10 bases from the 3' end of the first nucleic acid. However, this amendment to the claims does not overcome the present grounds of rejection because what constitutes the end of the first nucleic acid and the beginning of the second nucleic acid is not set forth in the claims and the claims include adaptors

which comprise a first nucleic acid sequence such that the nucleotides may be present flanking the 3' (and 5') terminus of the first nucleic acid. Accordingly, the claims are inclusive of the nucleic acid of Hudson which contains nucleotides flanking the TCCTT and CCCTT sequences.

**THE FOLLOWING ARE NEW GOUNDS OF REJECTION NECESSITATED BY
APPLICANTS AMENDMENTS TO THE CLAIMS:**

6. Claim 2 is rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Wang (US Patent No. 5,932,451).

Wang teaches a labeled nucleic acid consisting of:

5-'CCTGGGCCCTCCTGCT**TCCTT**-3' (referred to therein as SEQ ID NO: 2; see, for example, column 11). This nucleic acid comprises a topoisomerase I cleavage motif (i.e., TCCTT) which is not more than 10 bases from the 3' end of the nucleic acid.

Additionally, the sequences 5' of the CCCTT meet the limitations in the claim in that this 5' sequence (i.e., 'CCTGGGCCCTCCTGC') comprises a sequence which may be present within the multitude of possible intron sequences and also constitutes a polypeptide tag encoding sequence, a terminator sequence, and a fusible protein encoding sequence.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 4-10 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-10 and 22 are indefinite over the recitation of “and providing a scissile strand topoisomerase cleavage site that is not more than 10 bases from the 3’ end of the first nucleic acid.” It is not clear as to whether the scissile strand topoisomerase I cleavage site is intended to be the same as the ‘scissile strand topoisomerase I cleavage motif’ or whether the nucleic acid includes the cleavage site in addition to the motif. In the later instance, it is unclear as to what is intended to be the relationship between the cleavage motif and the cleavage site.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
August 19, 2003


CARLA J. MYERS
PRIMARY EXAMINER